

Ramirez, Angelica

Public Comment - Group 2

From: Andrew McCurry <dmccurry6@gmail.com>
Sent: Friday, August 27, 2021 5:05 PM
To: sbcob
Subject: Vaccine mandate



Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Aug. 27, 2021

Dear Board of Supervisors,

My name is Andrew McCurry and I am calling Greg Hart and all County Board of Supervisors to let them know they should oppose any County employee mandates regarding the vaccines.

- This action is an overreach of government and is an invasion of a person's privacy. It promotes hate, bigotry, and segregation against those who are medically disabled, immune compromised, or who have legitimate concerns over their health and the vaccine.

Furthermore, if you have ebola, hepatitis, shingles, MRSA, meningitis, conjunctivitis, diphtheria, pertussis, tuberculosis, chicken pox or cold/flu/cough you may still travel, go to work, go to school, go to a restaurant, go to a gym, go to a mall, go to the grocery store, go to the theater and go to concerts.

- California led the way in protecting the rights of those with HIV, an active communicable disease. Your actions today can defend the Constitution and individual rights of privacy or you can stomp on them. To quote former supervisor Peter Adams, " This Board does not take away American citizens bill of rights."

- This action promotes hate, bigotry, and segregation against those who are medically disabled, immune compromised, or who have legitimate concerns over their health and the vaccine. Do the right thing, the American way. Vote against mandated vaccines

Thanks,
Andrew McCurry

Sent from my iPhone

Ramirez, Angelica

From: Joy Cook <joycook@gmail.com>
Sent: Friday, August 27, 2021 5:36 PM
To: sbcob
Subject: Fwd: ADDENDUM to the Board of Supervisors August 31 Agenda includes consideration of Homeless Encampment Strategy, and COVID-19 Employee Vaccination/Testing Policy

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Hello,

Please provide my comments/requests to the board for consideration prior to them making decisions.

Item D1. Cannabis permitting. I would like to see some of the same restrictions used for for adult entertainment venues applied to Cannabis operations. For Cannabis farming I would like consideration given to areas zoned for farming where zoning changes have been made and the farmlands are now surrounded by residences. The time to consider impact to families is during zoning and permitting not after approval. For Cannabis there should be solid fencing required to make it more difficult for unauthorized access and to act as sound barriers especially if they will be using pest abatement that impacts the peaceful enjoyment of homes in the area. There should be automation required to ensure any pest abatement with noise shall be operated only during agreed times and sound walls high enough that to protect homeowners and nearby pets. Also any medical center/clinic that gets any county funding should require all to be vaccinated.

Item D5. Please consider mandatory vaccinations for all sheriffs department and childcare workers. The population these workers encounter on a regular basis are most likely to be unvaccinated and children that are not eligible for vaccination need to get as much protection as possible. So educators and day care providers need to be vaccinated as a condition of licensing and should be inspected. For those on county payroll they should pay extra for any health care coverage or temporary staff required to backfill their roles if they chose not to be vaccinated and then get COVID. I also don't think they should be eligible for long term disability if they choose not to get vaccinated and then get impacted. We need to do what is necessary to lead folks to make decisions to protect the health of all. Their choices should not be funded by taxpayer dollars.

Thank you for your consideration!

Joy Cook
805-714-0081

----- Forwarded message -----

From: County of Santa Barbara <sbcwebmaster@countyofsb.org>
Date: Thu, Aug 26, 2021 at 7:21 PM
Subject: ADDENDUM to the Board of Supervisors August 31 Agenda includes consideration of Homeless Encampment Strategy, and COVID-19 Employee Vaccination/Testing Policy
To: <joycook@gmail.com>

□

□

Ramirez, Angelica

From: Susan Anderson <supersea75@gmail.com>
Sent: Saturday, August 28, 2021 10:57 AM
To: sbcob
Subject: For the record re: August 31 Meeting
Attachments: -9174793754580037785.mp4

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear County of Santa Barbara:

The vaccine mandates are unconstitutional and unnecessary. There was never any reason to change our way of life over a disease with a 99% survival rate. Do you know what's happening in Europe? Millions and millions are protesting in the streets- from London to Paris to Rome.

No, We The People reject this tyranny that you obviously relish. And we will win this battle, lawsuit by lawsuit. Santa Barbara may be in a media blackout regarding the truth about COVID-19(84), but again let me tell you your policies are illegal and immoral.

Sincerely,
Susan Anderson

PS if you think locking down healthy people and closing schools is "public health" then you are sick people who deserve to be prosecuted for crimes against the community.

Ramirez, Angelica

From: Lee Heller <leehellerk9@gmail.com>
Sent: Saturday, August 28, 2021 1:37 PM
To: sbcob
Subject: Public Comment for item D5, Aug. 31, 2021

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear Chair Nelson and Members of the Board,

I am emailing in support of the proposed policy regarding County employees and COVID 19 protection.

This policy offers a reasonable accommodation for employees unwilling to be vaccinated against COVID 19, while promoting as much protection as possible for our community as a whole.

The proposed policy is not a 'mandate' to be vaccinated. If it were, employees would not have the alternative of being tested regularly. Although testing does not prevent transmission of the virus, it offers the County a tool for monitoring whether or not unvaccinated employees may be placing other workers, or the community at large, at risk. Such testing has been commonplace throughout the pandemic, including daily or near daily testing at the Trump White House (which mandated it for employees there), and by various sports teams. Indeed, the policy includes free testing by the County, so it does not even impose a financial burden on employees.

The claim that the proposed County policy is an excessive constraint on individual liberties thus does not hold up. But if there were no testing alternative, government mandated vaccination is still considered constitutional, as articulated by *Jacobson v Massachusetts*, which the current Supreme Court has let stand -- as witnessed by Justice Coney Barrett and the Court refusing to hear a suit against Indiana University's vaccination mandate. Where there is a pressing public health interest, as in the case of a highly transmissible and dangerous virus, the government interest in protecting the community outweighs the individual's right to refuse:

"The liberty secured by the Constitution of the United States does not import an absolute right in each person to be at all times, and in all circumstances, wholly freed from restraint, nor is it an element in such liberty that one person, or a minority of persons residing in any community and enjoying the benefits of its local government, should have power to dominate the majority when supported in their action by the authority of the State.

"It is within the police power of a State to enact a compulsory vaccination law, and it is for the legislature, and not for the courts, to determine in the first instance whether vaccination is or is not the best mode for the prevention . . . protection of the public health."

You here are "the legislature," determining that vaccination is indeed the best mode of preventing a highly transmissible virus -- now considered as transmissible as chicken pox, one of the most contagious viruses out there.

The fact is, county employees may interact with each other and community members in a range of settings and situations. Given how contagious the Delta variant is, unvaccinated employees pose a great risk of spreading COVID 19, including to underage children, immunocompromised individuals, and others who may be at risk of serious breakthrough infections. As such, they should be prevented from putting community members at risk, either by vaccination or by a monitoring protocol that reduces their ability to harm others.

Thank you for your consideration.

Lee E. Heller, Ph.D., J.D.
Santa Barbara CA

Ramirez, Angelica

From: Richard Solomon <rsolomon2@cox.net>
Sent: Saturday, August 28, 2021 1:43 PM
To: sbcob
Subject: Fwd: Covid-19 Update for Aug. 31 meeting

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

----- Forwarded message -----

From: **Richard Solomon** <rsolomon2@cox.net>
Date: Sat, Aug 28, 2021 at 12:44 PM
Subject: Covid-19 Update for Aug. 31 meeting
To: Das Williams <das_williams@hotmail.com>, Gregg Hart <gHart@countyofsb.org>, <jhartmann@countyofsb.org>, <bob.nelson@countyofsb.org>, <steve.lavagnino@countyofsb.org>

Dear Supervisors:

We are the board members of the Gray Panthers Santa Barbara Network and we write in enthusiastic support of a policy that all County employees be vaccinated against the Covid-19 virus as a condition of employment. We do not need to repeat the scientific facts and the reasons why a vaccine mandate is fully justified under the circumstances. The vaccines are safe, and there is no reason, except for demonstrated medical reasons, for County employees to not be vaccinated. The safest course is to allow the weekly testing option only for folks who, for valid medical reasons, cannot tolerate the vaccine.

The Gray Panthers Santa Barbara Network works both independently and in coalition with others to achieve social and economic justice, to promote a clean sustainable environment, to support quality and affordable health care, to create and maintain safe, affordable housing for all income levels as well as addressing other quality of life issues with special attention to older adults.

We have friends and relatives who are concerned about the community spread of the virus to vulnerable people, including the elderly, even if they are vaccinated. Vaccine mandates have been shown to reduce this risk.

Respectfully,

Richard Solomon, *Chair*
Gail Marshall, *Secretary*
David Landecker, *Treasurer*
Jan Keller, *Membership*
Richard Appelbaum
Jo Black
Marty Blum
Carol Keator

David Lebell, M.D.
Susan Rose
Janet Wolf



Educate. Advocate. Agitate.

Ramirez, Angelica

From: Laura Lucas <nihtsky@gmail.com>
Sent: Saturday, August 28, 2021 4:52 PM
To: sbcob
Cc: Nelson, Bob
Subject: Re: County Staff Vaccine & Mask Requirements

Follow Up Flag: Follow up
Flag Status: Flagged

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Copying the Clerk of the Board of Santa Barbara County for comments on Agenda Item D5, to be read into the record of the August 31, 2021 meeting.

Sent from Phone of Laura Lucas

On Aug 28, 2021, at 3:28 PM, Laura Lucas <NIHTSKY@gmail.com> wrote:

Hello Supervisor Nelson,

I am a constituent of yours in the City of Lompoc, CA.

I have heard that the Santa Barbara County Board of Supervisors are having public hearings on whether to enact mandatory COVID19 vaccinations and mask wearing for all county employees.

I fully support mandatory vaccinations with only the very strictest physician's excuse due to medical reasons. Absolutely no opt-out provisions for any reason! If an employee doesn't want to get vaccinated then they should be put on administrative leave without pay until they are fully vaccinated or they resign.

I fully support mandating masks to be worn by all employees during working hours, regardless of day or time of shifts.

I believe that every business has the right to establish their requirements as the owners determine appropriate and the public has every right to decide if they will comply in order to engage in activities with that business or not be allowed to by the owner.

These mandates are also absolutely necessary for publicly funded educational facilities, for students of all ages to wear masks and vaccinations as they are approved through the FDA EUA process. This is not a decision to be made by a parent or guardian. COVID vaccinations must be added to the list of vaccinations required to attend public schools.

In fact, I believe vaccinations should be mandatory for ALL Americans until the global pandemic is over when the SARS-CoV-2 virus and all variants have been eradicated globally! This is the only path to end mask mandates.

During a public health emergency, federal, state and local governments MUST follow the CDC advisories from scientific experts to protect citizens' lives. No one person can be allowed to put at risk another person's life and wellbeing. There should be civil fines and penalties of incarceration for repeat offenders who engage in behavior that poses a risk to another person.

Unfortunately, during this pandemic, stress has impacted all of us. It is obvious that the impact has made it apparent that mental illness can be underlying much of the opposition to the necessary steps we must take for all citizens be safe. There needs to be public mental health services to help people understand the situation and their emotional responses to reduce uncertainty and fears that contribute to public outbursts of anger and/or violent behaviors, which is unacceptable in our society.

Due to the global nature of this pandemic, Americans may never see the end of the SARS-CoV-2 viruses for the foreseeable future. This is not a political issue - it is a life and death issue for the whole world! It is past time for adults to accept reality and their personal responsibility for protecting our lives and the lives of our children. If Americans have the courage and fortitude to be the rational and logical example of taking the lead in eradicating these viruses, then the United States will truly be a global leader.

Please read my email on my behalf at the next public hearing and submit it into the public record for that County Board of Supervisors meeting.

Sincerely,
Laura J. Lucas
125 S 7TH ST
APT 219
Lompoc, CA 93436

Sent from Phone of Laura Lucas

Ramirez, Angelica

From: Michelle Holland <michellehollandsb@yahoo.com>
Sent: Sunday, August 29, 2021 9:14 AM
To: sbcob
Subject: Fwd: August 23, FDA 2021 Approval Letter
Attachments: image1.jpeg; ATT00001.htm; image0.jpeg; ATT00002.htm; August 23, 2021 Approval Letter - Comirnaty.pdf; ATT00003.htm

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Please see my email below to Superintendent Maldonado. Please research the information provided below and Vote no on mandates, otherwise you are literally participating in violations of international law. You can not mandate a drug that has not completed safety trials. An 8th grader could read the attached FDA document and conclude that the safety and efficacy outcomes will not be known until dates in the future, therefore whether or not authorities have labeled anything approved is putting the cart before the horse. Federal and State authorities will not come to your rescue when the finger pointing begins. You must think for yourselves, interpret data for yourselves, and be personally responsible for the leadership you provide at this time. Throughout history, it has taken good people to stand up in the face of power and greed to turn the tide. It may be uncomfortable to question authority, but there has never been a more important time to do exactly that.

Michelle Holland

Begin forwarded message:

From: Michelle Holland <michellehollandsb@yahoo.com>
Date: August 29, 2021 at 8:58:10 AM PDT
To: hmaldonado@sbunified.org
Subject: August 23, FDA 2021 Approval Letter

Hello Hilda,

Attached is the actual approval letter from the FDA for the pfizer vaccine.

Please look closely at the dates for completion of the various safety and effectiveness studies included in the FDA document. The studies conclude between 2022 and 2025.

You are having on campus vaccine clinics (next one at Franklin school) and representatives from the district and county are telling the community in English and Spanish that the Pfizer vaccine is "fully approved" and "safe."

You are not getting informed consent from trusting parents who look up to you and are trusting you with the health of their children when you are not disclosing the fact that the experiments are not yet complete and it should be their choice whether to have their children participate or not. In fact, the school district is doing everything in it's power to pressure students and teachers to take it.

A medical product can not be deemed safe (by logic or fact) before the safety studies are complete. Bloomberg just announced a study that people with natural immunity from a previous case of Covid have stronger immunity against the Delta variant than vaccinated individuals. Many of your students have already had Covid, so pressuring anyone to get a vaccine now that we know natural immunity is superior makes no sense and could be harmful as the VAERS numbers suggest. It should be a choice. It is recognized in the pfizer application documents that the vaccine does not stop transmission (it only purports to lesson the symptoms for the individual taking it) so your flyer for the Franklin clinic is also misleading in that regard.

You don't protect "your friends and community" by getting the shot. If you doubt this, have public health show you the vaccine applications and all relevant studies proving the vaccines stop transmission. They won't be able to provide it.

Data from 7 months of global vaccines is showing the opposite. Viral load is higher in vaccinated individuals and global data shows the most vaccinated countries have the highest new case counts. Data is showing that somehow vaccination is accelerating the spread.

Why have the authorities you trust to guide you on these matters misinterpreted data? I don't have the answer to that. What could possibly be motivating them to push a billion dollar enterprise that wants to make everyone customers for life by mandating boosters into eternity, especially when data shows that they are more harmful and less effective (especially for children and young adults) than natural immunity?

If I were in charge of the health and safety of students in my district, I would demand the public health numbers on total hospitalizations and deaths from Covid in each age group in the county and then I would demand any and all information on injuries and deaths reported from the vaccine in the county. Then I would ask a few common sense questions from the data.

Did our total deaths and hospitalizations go up in the county? If we did not see a statistically significant increase from Covid deaths in 2020 compared to previous years, this does not indicate a local emergency.

Did we have more children and young adults suffering from Covid deaths and complications, or did we have more children and young adults suffering adverse side effects from the vaccine? Nationwide, have we had more youth deaths from the vaccine or from Covid? I already know the answer to that and the answer remains consistent nationwide..but the question is why are you not aware of that information? If you did know the answer, surely you would not push ahead with the path the district is on.

This ends when individual leaders in the community choose a side. You either choose the side of willful ignorance and keep outsourcing the truth to higher authorities, or you take responsibility for educating yourself on the risks vs benefit and make the best decisions for your local community. History will not look kindly on those that choose willful ignorance. "I was just following orders" never has aged well in the past.

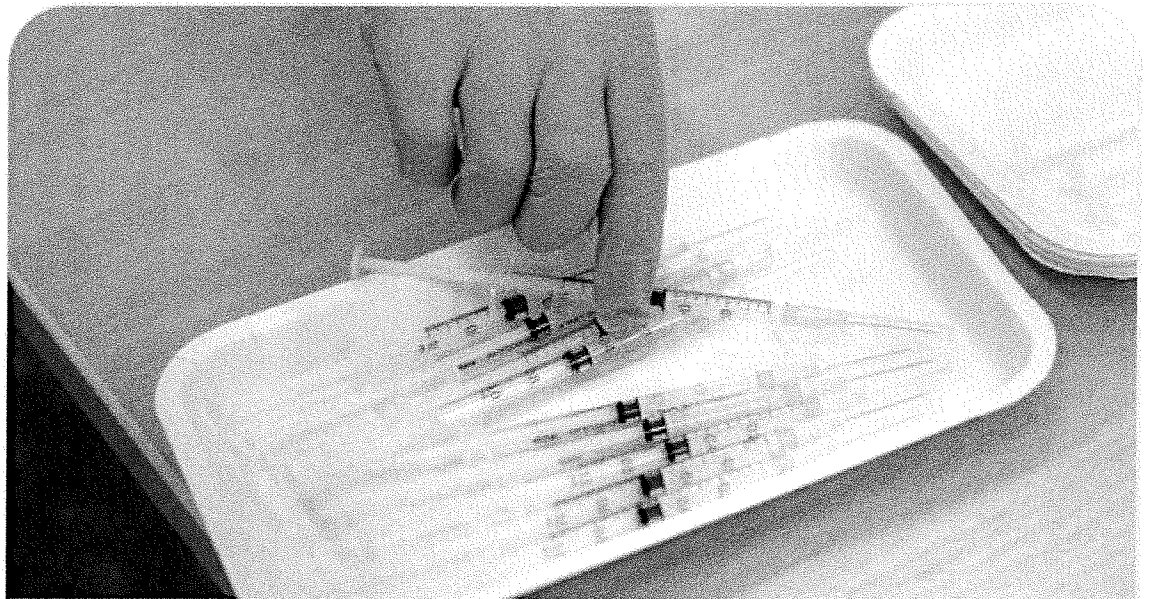
This is a moment in time where individuals can be heroes or they can be cowards and get in line.

Michelle



Bloomberg ✓ @business · Aug 26 ...

People who recovered from a bout of Covid-19 during one of the earlier waves of the pandemic appear to have a lower risk of contracting the delta variant than those who got two doses of the vaccine from Pfizer



Previous Covid Prevents Delta Infection Better Than Pfizer Shot

[bloomberg.com](https://www.bloomberg.com)

FREE COVID-19 VACCINATION CLINIC

PFIZER(12+) and J&J (18+)

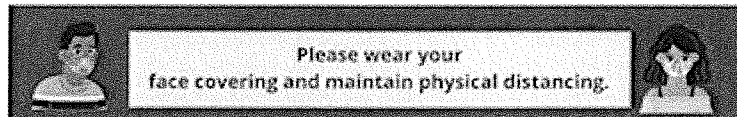
**LOCATION: Franklin Elementary
School**

1111 E MASON ST
SANTA BARBARA, CA 93103

DATE: Wed, September 8th
4:00PM - 7:30PM

NO APPOINTMENT NECESSARY

PROTECT YOUR FRIENDS & COMMUNITY.



PublicHealthSBC.org





Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at (b) (4)

The final formulated product will be manufactured, filled, labeled and packaged at Pfizer (b) (4)

The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at (b) (4)

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.

We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90°C to -60°C (-130°F to -76°F). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at (b) (4) _____), the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer (b) (4) _____, it is defined as the date of the (b)(4) _____

Following the final sterile filtration, (b) (4) _____

, no

reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) _____ when stored at (b) (4) _____. We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at <https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations>:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines>. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm>.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an “**Annual Status Report of Postmarketing Study Requirement/Commitments**” and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

Final Protocol Submission: October 7, 2020

Study Completion: May 31, 2023

Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

Final Protocol Submission: February 8, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

Final Protocol Submission: January 31, 2022

Study Completion: July 31, 2024

Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 31, 2021

Monitoring Report Submission: October 31, 2022

Interim Report Submission: October 31, 2023

Study Completion: June 30, 2025

Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: January 31, 2022

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: June 30, 2022

Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm>.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

12. Study C4591012, entitled “Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran’s Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine.”

Final Protocol Submission: January 29, 2021

Study Completion: June 30, 2023

Final Report Submission: December 31, 2023

13. Study C4591014, entitled “Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California.”

Final Protocol Submission: March 22, 2021

Study Completion: December 31, 2022

Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm>.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Ramirez, Angelica

From: Jose Alvarez <sound5150@aol.com>
Sent: Sunday, August 29, 2021 11:48 AM
To: sbcob
Subject: Vaccine Mandate

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Board Of Supervisors,

This is regarding your decision to move forward with the vaccine mandate for all county employees. I am among many other county employees who are against the vaccine mandate. It doesn't matter if you are in favor of the vaccinated or not, but you are taking away everyone's freedoms of choice. This is a freedom many of us have fought for Americans to maintain through military service and now public service.

I also know first hand that the county already has several deputy vacancies that cannot be filled and with the rapid increase in crime throughout the state and Santa Barbara County, you are playing with fire and the safety of our residents by mandating the vaccine on your deputies. I don't think I need to remind you of the increase in homicides, thefts, burglaries, domestic violence, accompanied with the release of felons residing in Santa Barbara County. Try managing the increase in violent crimes with only half of your law enforcement.

Your desire to make a life altering decisions for us will cause several deputies to be terminated from employment as we will not submit to your vaccine mandate, I being one of those not getting the vaccine. I will force the county to terminate my employment so I can collect unemployment which in turn will cost you in addition to having to exhaust resources and expenses to hire more deputies without my qualifications and experience. Not to mention the amount of law enforcement applicants has dropped drastically due to the negative perception of law enforcement officers that has been brought upon us. In years past, you would have had the argument of saying, "We could always hire someone to replace you", but you and I both know that is no longer the case. You are not financially secured nor have the luxury of time to deal with the expense of having to do background investigations, pay for the cost of sending new hires to the academy, and training them to replace the amount of deputies you will be forced to let go. Don't forget, those of us who will be let go are your field training officers that the county depends on to train the new deputies.

Additionally, let me point out that having a copy of your most recent requirements for unvaccinated county employees is beneficial to us "unvaxxed". Your own directive pays out a solid foundation to file a discrimination suit against the county. It has been proven that fully vaccinated people can still get and spread COVID, yet your requirement only requires unvaccinated county employees to get tested once or twice a week. Your weekly COVID testing and previous requirements for only unvaccinated employees to wear a mask at work can be paralleled to a modern-day Scarlet Letter.

I hope you think long and hard before making a decision that will force a mass exodus from the Santa Barbara County Sheriff's Office.

Respectfully,

Jose Alvarez
Santa Barbara County Deputy Sheriff.

Ramirez, Angelica

From: Lata Murti <latamurti@gmail.com>
Sent: Sunday, August 29, 2021 4:22 PM
To: sbcob
Subject: Public Comment on Item D5, Aug. 31 County Board of Supervisors Meeting

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear Santa Barbara County Board of Supervisors,

I am writing to ask that you vote in favor of the policy that all Santa Barbara County employees undergo regular COVID-19 testing or be vaccinated against the virus.

I am asking this not only as a concerned resident of the county, but also as a college professor of sociology. Along with several other academics in California, I am currently writing about the impact of COVID-19 on socially vulnerable communities. These communities include our children, many of whom are too young to be vaccinated. The best way to protect these youth from the COVID-19 virus is to make sure the adults who interact with them on a daily basis are vaccinated or are not carrying the virus.

Among these adults are Santa Barbara County Probation Officers, many of whom work in juvenile residential programs like Dos Puertas School in Santa Maria and Los Prietos Boys' Camp in Santa Barbara. Indeed, the juveniles in these programs interact with County Probation Officers more than members of their own families. And while some are too young to be vaccinated, others likely do not have ready access to COVID-19 testing or the vaccine given their circumstances and situations.

It is imperative, then, that Santa Barbara County Probation Officers be regularly tested or vaccinated in order to help stop the spread of COVID-19 in juvenile residential facilities. Already, before COVID-19 vaccines became available, we saw how quickly the virus spreads in juvenile halls and jails. Now we have a way to stop the spread—by asking that all Santa Barbara County employees be tested or vaccinated against COVID-19.

So, I ask that you please vote to approve this policy. The lives of our county's most vulnerable populations depend on it.

Thank you.

Sincerely,
Lata Murti, Ph.D.

Ramirez, Angelica

From: Big Introvert <bigintrovert@protonmail.com>
Sent: Sunday, August 29, 2021 6:56 PM
To: sbcob
Subject: Upcoming Vax or Test Mandate

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Hello Supervisors,

My name is Tracee and I'm a Deputy with the County Sheriff's Office. I'm one of the Crisis Intervention co-response Deputies.

I love my job. That being said, I will walk away from it if this mandate is imposed. To be clear, I am not against vaccines. But this is not a vaccine. Vaccines protect you from getting a disease. These shots do not do that. They may they lessen the symptoms, but they don't stop the recipient from contracting or spreading the virus. I've watched enough of these supervisor meetings to know how many medical professionals have told you about many of the serious and sometimes deadly side effects that people are having from this covid shot. So I'll stick to what I know. (If you're interested in more opinions from doctors, please check out this website. <https://americasfrontlinedoctors.org/summit/> I specifically recommend the not-too-long presentations by virologist Dr Ryan Cole, and Navy Dr Lee Merritt.)

The legal standing behind this mandate is based upon case law from 1905. In 1905, infectious diseases were the leading cause of death. There was no FDA, no regulation of research, and no doctrine of informed consent. The case law arose from smallpox vaccines. Smallpox had a mortality rate of 30%. Do you remember what the mortality rate of covid is? It's less than 1%. Based on the totality of these circumstances, it seems these cases are incongruent.

There are additional cases that support the 1905 case, but they're specific to vaccinations at schools. That's pretty different, too. There's even been the citing of the SCOTUS docket 21A15, also about a school mandating the covid shot. The case isn't named because it was not heard. A case not being heard does not mean it was dismissed, or that it was invalid, etc. There are a lot of reasons for cases not being heard and it doesn't mean a case can't be heard at a later date.

All of the cases that support the 1905 case were about vaccinations that had completed their clinical trials. Despite FDA approval, clinical trials are not complete for any of the covid shots. That's quite a gamble with the county's money - taking on the liability for any associated health issues of these shots. And for how many employees?

But you say we have the option to test and mask instead of get the covid shot. When I pull over someone suspected of DUI, I legally cannot coerce them to give me a breath or blood sample. Taking someone's breath is a search. Each person has the right to refuse. In those situations, I have to get a warrant. I have yet to find a case law that would support these forced searches for a test of someone when there are other treatments available, and no crime has been committed. But there are a TON of case laws that apply to needing a warrant for any search.

This mandate is under the guise "public safety" concerns. But I don't think you understand how secure our 4th amendment has been kept throughout the years. If any victim of a crime, a healthcare professional, firefighter, or law enforcement officer were injured during fight, or stuck by a needle during a search, I would need a warrant to find out if the person arrested was HIV positive or not. There are examples of these situations within this county within the last few weeks. In order to acquire any bodily fluid from any inmate regardless of the suspected crim who is already housed in one of our jails, we cannot get the bodily fluid without consent or a warrant.

I haven't even touched on the discriminatory aspects of mask wearing being mandated for only those who have not taken the shot, even though those who have taken the shot can transmit the virus just as easily - per the CDC. If I'm not mistaken, medical discrimination is covered under the Civil Rights Act.

For the sake of the department, the county finances (several Deputies are already seeking legal advice), and the safety of the county, please do not push forward with this mandate.

To be clear. I love my job. But I will not get the covid shot. I will not consent to repeated searches of my person. I refuse. I'm not alone.

Again, I love my job. I don't want to be fired. Please do not impose these mandates.

Sent with [ProtonMail](#) Secure Email.

Ramirez, Angelica

From: Janice Keller <jkeller2002@msn.com>
Sent: Sunday, August 29, 2021 8:51 PM
To: Nelson, Bob; Williams, Das; Hart, Gregg; Hartmann, Joan; Lavagnino, Steve; sbcob
Subject: Re: Addendum Item No. 5 (Human Resources) - Employee Vaccination and Testing Policy
Attachments: Letter to BoS.pdf

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

*JANICE KELLER
P.O. Box 504
Lompoc, CA 93438-0504
(805) 291-9777*

August 29, 2021

Bob Nelson, Chair
Santa Barbara County Board of Supervisors
511 East Lakeside Pkwy., Suite 47
Santa Maria, CA 93455

RE: Addendum to Human Resources Agenda, Item No. 5 (Employee Vaccination and Testing Policy) for August 31, 2021 BoS Meeting

Dear Supervisor Nelson,

I have been a Lompoc resident for the past 33 years and a County resident for over 50 years. It is very important to me that the County Board of Supervisors uphold its duty to protect the residents of the County. Therefore, I urge you and the other Supervisors to adopt a policy that all County employees be vaccinated against COVID-19 subject only to an exception for those who, for valid medical reasons, should not be vaccinated. For those who meet this exception, the testing process recommended by staff must be required in lieu of being vaccinated.

Thank you in advance for your action to help curtail this pandemic.

Sincerely,

/s/

Janice Keller

cc. Das Williams
Gregg Hart

Joan Hartmann
Steve Lavagnino
Clerk of the Board

JANICE KELLER
P.O. Box 504
Lompoc, CA 93438-0504
(805) 291-9777

August 29, 2021

Bob Nelson, Chair
Santa Barbara County Board of Supervisors
511 East Lakeside Pkwy., Suite 47
Santa Maria, CA 93455

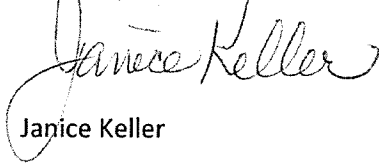
RE: Addendum to Human Resources Agenda, Item No. 5 (Employee Vaccination and Testing Policy) for August 31, 2021 BoS Meeting

Dear Supervisor Nelson,

I have been a Lompoc resident for the past 33 years and a County resident for over 50 years. It is very important to me that the County Board of Supervisors uphold its duty to protect the residents of the County. Therefore, I urge you and the other Supervisors to adopt a policy that all County employees be vaccinated against COVID-19 subject only to an exception for those who, for valid medical reasons, should not be vaccinated. For those who meet this exception, the testing process recommended by staff must be required in lieu of being vaccinated.

Thank you in advance for your action to help curtail this pandemic.

Sincerely,



Janice Keller

cc. Das Williams
Gregg Hart
Joan Hartmann
Steve Lavagnino
Clerk of the Board

Ramirez, Angelica

From: Tahara Ezrahti <tezrahti@hotmail.com>
Sent: Monday, August 30, 2021 11:59 AM
To: sbcob
Subject: Vaccine Mandates

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear Santa Barbara County Board of Supervisors,

I am a life long Democrat and environmentalist and have lived in Mr. Hart's district for 21 years. I am writing to express my opposition to vaccine mandates of any sort! Everyone who wants a vaccine has had a chance to get it. The people who have not chosen to inject themselves with a liability free, experimental, medical product that does not stop infection or transmission have determined that the risks outweigh the benefits and in a free society that has to be the choice of the individual.

To mandate unwanted medical treatments is a kin to slavery. This may sound like an extreme analogy to people who think taking a jab is no big deal but we are talking about the principle of bodily integrity. When citizens of the United States of America are not free to determine what is injected into their bodies and the bodies of their children they have lost ownership over their bodies and are therefore slaves.

I ask you to be on the right side of history and take your oath of office and Pledge of Allegiance seriously. Standing for "liberty and justice for all" includes people who do not want forced medical procedures. I will vote for and support candidates, regardless of party, who support freedom and medical choice. It is the most important issue of our day.

Thank you for your time.
Sincerely,
Tahara Ezrahti

Sent from [Mail](#) for Windows

Ramirez, Angelica

From: Gretchen Murray <mur47@yahoo.com>
Sent: Monday, August 30, 2021 12:07 PM
To: sbcob
Subject: concerning COVID immunity status

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

When drafting the vaccine status requirements, one additional category should be for those who have recovered from the infection. Their natural immunity is at least as strong as the immunity induced by any of the mRNA immunizations.

Kind regards,

Gretchen Murray, Ph.D. (retired)

Ramirez, Angelica

From: kathleenmackins@aol.com
Sent: Monday, August 30, 2021 12:17 PM
To: sbcob
Subject: Vaccine Mandates

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

I strongly encourage you to vote AGAINST any vaccine mandates. If any of you truly study the science you will see that the vaccine can be a help initially but the long term downsides are only now starting to manifest themselves.

This is America and freedom of choice is something we cherish. Please do not go down this road.

Thank you!

Kathleen Da Ros Mackins
4639 Gerona Way
Santa Barbara, CA 93110

Ramirez, Angelica

From: Michael Holland <michael@bainbridgehomes.com>
Sent: Monday, August 30, 2021 12:20 PM
To: sbcob
Subject: Read it, know it, protect yourself from violating the law- no mandates!
Attachments: BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf; ATT00001.txt

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

>
> Read this international law and then count the ways a mandate for a covid vaccine violates this law.
> And then think about your own personal liability for violating this law. Who is going to come save you if you are found in violation?
>
> Michael Holland

Introduction

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

This judgment established a new standard of ethical medical behaviour for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

This code also recognizes that the risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.

This code recognizes that doctors should avoid actions that injure human patients.

The principles established by this code for medical practice now have been extended into general codes of medical ethics.

The Nuremberg Code (1947)

Permissible Medical Experiments

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is

a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

For more information see [Nuremberg Doctor's Trial](#), *BMJ* 1996;313(7070):1445-75.

Ramirez, Angelica

From: Jamie Davin <jamiemdavin1@gmail.com>
Sent: Monday, August 30, 2021 1:20 PM
To: sbcob
Subject: Public Comment: BOS Meeting 8/31/21

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Hello,

I have requested the SB County data that supports the current mask mandate and I have yet to receive it. The Public Health Department wrote me back stating they did not have any information that supports my questions. Does the county not have any data? How can we be mandating masks and not have any information to support it?

Also, I am wondering how mandating the current covid vaccine will improve our community's health as the vaccine does not stop transmission against Delta? Israel is experiencing a huge influx of Delta amongst their highly vaccinated populations, with the vaccinated being the most hospitalized. The Board needs to explain and show how it can justify a mandate using science and real-world data. It feels like the Board is following suit just for optics, instead of making decisions based on scientific proof.

If the Board is preparing to violate citizens rights of bodily autonomy and personal health decisions with the threat of job termination, the burden of proof is on the Board to demonstrate the overwhelming need to do this as well as showing how it will have a beneficial outcome. The Board needs to show how the benefits outweigh the massive harms this mandate will cause.

thank you,
Jamie Davin

Ramirez, Angelica

From: Gretchen Murray <mur47@yahoo.com>
Sent: Monday, August 30, 2021 12:23 PM
To: sbcob
Subject: Re: concerning COVID immunity status

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Please link to this NIH website for scientific information concerning lasting innate immunity

<https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19>

Gretchen Murray

On Monday, August 30, 2021, 12:07:19 PM PDT, Gretchen Murray <mur47@yahoo.com> wrote:

When drafting the vaccine status requirements, one additional category should be for those who have recovered from the infection. Their natural immunity is at least as strong as the immunity induced by any of the mRNA immunizations.

Kind regards,

Gretchen Murray, Ph.D. (retired)

Ramirez, Angelica

From: Daimen Vazquez <ffdaimen@gmail.com>
Sent: Monday, August 30, 2021 1:51 PM
To: sbcob
Subject: Covid-19 mandates

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

To the board of supervisors,

I am a public servant, like you, and I'm writing this email in opposition to any covid-19 related injections. Currently, the covid-19 disease is not a pandemic. It is an endemic, as countries like India and Mexico have "flattened their curve." However, this flattening has been shown to spike again, which mimics another respiratory virus: the flu. What we're seeing with these "waves" of infections parallel the seasonal flu. Look at your own handout from last week, showing 3 different spikes. Compare that with any seasonal flu graph and they're virtually identical. We are dealing with a seasonal respiratory virus. And what is the guidance for that? Stay home until you're better, get plenty of rest, fluids. Why, then, are you treating this new seasonal respiratory virus any differently? The People have a choice to get a flu shot. Give them this option again.

AGAIN, this is a HIGHLY SURVIVABLE disease. I don't know anyone directly who has died from covid-19. I don't know anyone who's died from the flu. That's how rare it is from which to die. I DO however, know 2 people who have had it, both with risk factors and comorbidities. One was an obese 40 year old who was on a ventilator and still suffers from respiratory effects. The other is my wife's 83 year old grandfather who has COPD and smoked for 40 years...with zero deficits.

Of all the people who became infected at my job, in the county of Santa Barbara, zero have deficits and zero died. Why? Because it doesn't affect healthy, young, active people like it does the elderly and those who are immuno-compromised or with co-morbidities.

The current mask policy in Santa Barbara County is a face covering which doesn't protect against this disease. Your policy contradicts what you know and itself. Only an N95 that has been properly mask-fitted and used with a particle generator and specific software protects-and that's only UP TO 95% (hence the "95" in N95). So to truly protect The People you serve, you should only ASK them to wear a P100 mask or any closed-circuit breathing system (SCBA, APR, PAPR, etc.). If you're going to follow the science, do it fairly.

The Israel model of covid-19 strategies was talked about last week. That is one way to handle it: fear; coercion; mandates. But if a model is to be cited, then the inverse of that model must also be talked about. Sweden has been very progressive in the way the government deals with the endemic disease. they never had lockdowns, never had mandates, but still offered the injection as a CHOICE to its people. They suffered deaths, like every other measure failed to prevent and like every other country was unable to avoid, but they challenged the fear-based method of attack (that has caused this country to dive into another moment of division and segregation, fueled by policies and tactics which you are likely to implement) with rationale and logic. Their chief epidemiologist (root word "epidemia", not pandemiologist) believed in Man's immune system and won. He challenged this disease with herd immunity...and won. Vaccination is NOT the only way to achieve herd immunity. But it is a way for indemnified pharmaceutical companies to make billions more dollars. That man, Anders Tegnell, paid the price, initially, of being chastised due to the initial impact. But he wasn't afraid to lose favor, knowing he did the right thing. Therefore, I say to you, don't fear losing your seat to do the right thing. Your seat is only temporary, but you can be a true hero by choosing in favor of The People whom you serve.

<https://www.aier.org/article/sweden-despite-variants-no-lockdowns-no-daily-covid-deaths/>

Last week someone also mentioned that artificial immunity is better than natural immunity. This is blatantly false, as was heard amongst the many medical professionals in attendance. Any medical professional who says that should not be trusted. One example is that a pregnant woman passes on her antibodies to the fetus during the last trimester. Why would that happen? Because the human body does what's best for itself and the life it produces. That is basic science.

How can you mandate an experimental injection to The People of which the manufacturers filed indemnity? Doesn't that concern you? Who, then, do The People you serve turn to when they do get an adverse reaction? And they will get an adverse reaction, hopefully not lasting or life-changing. These reactions include: anaphylaxis; Guillain-Barre Syndrome; thrombosis, causing pulmonary embolism, strokes and heart attacks; pericarditis and myocarditis (inflammation of different parts of the heart); death. None of those are caused by acquiring covid-19, save death. These facts are from the CDC's own website, which cites VAERS. And VAERS is a reporting system from The People. Not every person who has an adverse reaction reports to this system, speculated to be near 1% of actual numbers. Therefore, nearly 7,000 deaths from the injection multiplied by 100 equals 7 million deaths potentially. I don't believe that number, but I do believe that there are plenty of people who are not reporting severe adverse reactions to this injection. That means the deaths alone are lower than the real numbers. To FORCE The People to be subject to any of these adverse reactions is morally wrong and you should be ashamed of yourselves for considering a mandate. This issue is about CHOICE only.

In 1976, the government mandate a vaccine against the swine flu and it backfired. Why did it backfire? It was partly due to the linked deaths and dozens of Guillain-Barre Syndrome cases. Also, because of the lack of trust that was growing daily in the eyes of The People. The effort to vaccinate the entire nation was suspended and seen as buffoonery these days. History has taught us to not repeat our past blunders, but here we go again. One major difference: "It began when the industry manufacturers announced that they had been refused liability insurance, effectively downing tools. They asked Congress to indemnify them, but were turned down."

<https://www.bbc.com/future/article/20200918-the-fiasco-of-the-us-swine-flu-affair-of-1976>

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>

<https://greatmountainpublishing.com/2021/04/05/new-study-confirms-the-vaers-system-is-only-reporting-approximately-1-of-anaphylaxis-from-covid-19-vaccines/>

If those injected to fight this disease and those not injected are still acquiring and spreading the disease, why then mandate something that causes so much harm? I've never shown a single symptom of covid-19, yet I'm potentially exposed everyday at work to symptomatic and asymptomatic carriers. Am I, then, a supreme marvel of genetics? Am I supremely lucky? Perhaps it's because I am young, healthy, active with no co-morbidities and take the proper precautions to minimize my susceptibility and acquisition. Perhaps with education and logic, I've been able to stay healthy, like millions of Americans.

Using the CDC's own numbers and simple math allows for a near 99% survivability rate. That's including those with one or more risk factors, most that die having 3 or more risk factors.

https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

This is not an argument against vaccination. My wife, children and I are vaccinated against many things, many deadly things. Covid-19 is deadly, but not as deadly as cigarette smoking. Yet you allow The People to continue with that lifestyle with not a peep. This seasonal respiratory virus is not as deadly as heart disease, but you allow The People to continue with a sedentary lifestyle and poor diet? Why the hypocrisy? To implement a mandate is to be a hypocrite. You don't truly care about your constituents and their health. You care solely about re-election and power and imposing your will and your feelings upon people.

To implement this mandate is to scoff at the opinion and experience of so many medical professionals in attendance last week. A man said he would quit after being a doctor for 34 years. You would risk all of that knowledge and experience, and take it away from The People by forcing an injection that has many adverse reactions, is losing its efficacy daily, and is NOT PREVENTING ACQUISITION OR TRANSMISSION OF COVID-19. Furthermore, it's dividing this nation yet again. The CDC director herself said that the vaccines do not stop people from transmitting the disease.

https://www.realclearpolitics.com/video/2021/08/06/cdc_director_vaccines_no_longer_prevent_you_from_spreading_covid.html#!

A final thought: when does it end? When will you be satisfied with your actions? When will you stop attempting to over-reach with your power THAT IS GRANTED TO YOU BY THE PEOPLE? This disease will not go away. We will gain herd immunity and the only lasting memory will be of those elected into positions of power and how they helped The People.

Daimen Vazquez

Ramirez, Angelica

From: Thais Marlier <thaiskitchen@icloud.com>
Sent: Monday, August 30, 2021 2:22 PM
To: sbcob
Subject: Please read

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear County Board of Supervisors,

My name is Thais Marlier- My relationship to SB County. My employment ___Small business owner___.

Buried in the fine print of Monday's approval by the U.S. Food and Drug Administration of the Pfizer Comirnaty COVID vaccine are two critical facts that affect whether the vaccine can be mandated, and whether Pfizer can be held liable for injuries.

The press [reported](#) that [vaccine mandates](#) are now legal for military, healthcare workers, college students and employees in many industries.

First, the FDA acknowledges that while [Pfizer](#) has “insufficient stocks” of the newly licensed Comirnatyvaccine available, there is “a significant amount” of the Pfizer-BioNTech COVID vaccine — produced under [Emergency Use Authorization](#) (EUA) — still available for use.

The FDA [decrees](#) that the Pfizer-BioNTech vaccine under the EUA should remain unlicensed but can be used “interchangeably” ([page 2, footnote 8](#)) with the newly licensed Comirnaty product.

Second, the FDA pointed out that the licensed Pfizer Comirnaty vaccine and the existing, EUA Pfizer vaccine are “legally distinct,” but proclaims that their differences do not “impact safety or effectiveness.”

There is a huge real-world difference between products approved under EUA compared with those the FDA has fully licensed.

EUA products are [experimental](#) under U.S. law. Both the [Nuremberg Code](#) and federal regulations provide that no one can force a human being to participate in this experiment. Under [21 U.S. Code Sec.360bbb-3\(e\)\(1\)\(A\)\(ii\)\(III\)](#), “authorization for medical products for use in emergencies,” it is unlawful to deny someone a job or an education because they refuse to be an experimental subject. Instead, potential recipients have an absolute right to refuse EUA vaccines.

U.S. laws, however, permit employers and schools to require students and workers to take licensed vaccines.

EUA-approved COVID vaccines have an extraordinary liability shield under the [2005 Public Readiness and Preparedness Act](#). Vaccine manufacturers, distributors, providers and government planners are immune from liability. The only way an injured party can sue is if he or she can prove willful misconduct, and if the U.S. government has also brought an enforcement action against the party for willful misconduct. No such lawsuit has ever succeeded.

The government has created an extremely stingy compensation program, the [Countermeasures Injury Compensation Program](#), to redress injuries from all EUA products. The program’s parsimonious administrators have compensated [under 4% of petitioners](#) to date — and not a single COVID vaccine injury — despite the fact that physicians, families and injured vaccine recipients have reported more than [600,000 COVID vaccine injuries](#).

At least for the moment, the Pfizer Comirnaty vaccine has no liability shield. Vials of the branded product, which say “Comirnaty” on the label, are subject to the same product liability laws as other U.S. products.

When the Centers for Disease Control and Prevention’s (CDC) Advisory Committee for Immunization Practices places a vaccine on the mandatory schedule, a childhood vaccine benefits from a generous retinue of liability protections.

But licensed adult vaccines, including the new Comirnaty, do not enjoy any liability shield. Just as with [Monsanto’s herbicide Roundup](#), people injured by the Comirnatyvaccine could potentially sue for damages.

And because adults injured by the vaccine will be able to show that the manufacturer knew of the problems with the product, jury awards could be astronomical.

Pfizer is therefore unlikely to allow any American to take a Comirnaty vaccine until it can somehow arrange immunity for this product.

Given this background, the FDA’s acknowledgement in its approval letter that there are insufficient stocks of the licensed Comirnaty, but an abundant supply of the EUA Pfizer BioNTech jab, exposes the “approval” as a cynical scheme to encourage businesses and schools to impose illegal jab mandates.

The FDA’s clear motivation is to enable Pfizer to quickly unload inventories of a vaccine that science and the [Vaccine Adverse Events Reporting System](#) have exposed as unreasonably dangerous, and that the [Delta variant](#) has rendered obsolete.

Thais

Ramirez, Angelica

From: G W <gordonrwilliams3@gmail.com>
Sent: Monday, August 30, 2021 2:31 PM
To: sbcob
Subject: Vaccine Mandate

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Hi, I'm Gordon Williams, I served in the United States Army for 20 years and now I'm serving the County of Santa Barbara as a Sheriff's Deputy.

Eighteen months ago when the world shuttered in and sheltered in place. When there were more questions than answers, first responders and front line workers ran into the unknown, no questions asked and with minimal PPE, while the majority of people stayed home.

We went to work. We continued because that's what we do. We save lives, we help people, we run into burning buildings, and we protect citizens. Because of us, your community is safer. We put ourselves and our lives on the line every day for this community.

Now is your opportunity to advocate for us, to champion for us, to protect those who protect and serve you and your families.

We have been serving this community for the last 18 months and we'd like to just continue doing our jobs. We are already in a health crisis do not create another public crisis by mandating this vaccine and testing by potentially pushing us out of jobs that we love and keep us from serving our communities.

Now is your chance to be our hero.

It is my understanding that you are proposing all unvaccinated county employees be tested weekly. Vaccinated employees however can bypass this requirement even though they too can contract, carry, and spread COVID-19.

In regards to testing, PCR testing has now been proven to be faulty and inaccurate at times. Thus creating false positives and false negatives.

Make it make sense.

Numerous county employees have already been infected with and recovered from COVID-19. I am curious if the county is following the re-infection rates of those employees. It is my understanding that the Santa Barbara County Health Department is not. Numerous studies are indicating that prior infection gives lasting immunity. I am not a scientist or a doctor but I am college educated and I can read data from which scientists and doctors have published.

We do not know the consequences of the vaccine or natural infection. This is a new virus that the entire world is trying to navigate and understand, and we are just trying to make the best-informed decision for ourselves and our families, without mandates.

Thank you for your time.

Gordon

Ramirez, Angelica

From: Edle Hatletveit <levsunt@yahoo.com>
Sent: Monday, August 30, 2021 2:48 PM
To: sbcob
Subject: Vote NO on mandates

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Where there is risk, there must be consent

Sent from my iPhone

Ramirez, Angelica

From: Lupita Navarrete <lupi187@gmail.com>
Sent: Monday, August 30, 2021 2:57 PM
To: sbcob
Subject: V Mandate

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear,

Santa Barbara Board of Supervisors,

Please Vote against Vaccine Mandates.

This has & continues to create hate and segregation that's widely accepted in society. This is wrong.

The role of the government and its representatives is to serve and represent the people. I am one of many that asks you to seriously consider our voice.

Mandating a shot violates our basic human right as well as our constitutional rights.

--

Blessings Lupita Navarrete-Ruiz UC Santa Barbara Graduate 2016

Ramirez, Angelica

From: OSCAR CARMONA <ocarmona@cox.net>
Sent: Monday, August 30, 2021 3:23 PM
To: sbcob
Subject: Letter against vaccine mandates

Caution: This email originated from a source outside of the County of Santa Barbara. Do not click links or open attachments unless you verify the sender and know the content is safe.

Dear Santa Barbara County Board of Supervisors,

I am a lifelong Democrat and environmentalist and have lived in Mr. Hart's district for 21 years. I am writing to express my opposition to vaccine mandates of any sort! As a Latino voter I am appalled at the notion that we Latinos who have not opted to take the Covid "vaccine" are labeled as vaccine hesitant. For myself and many other Latinos that I personally know, the choice is simple, we do not want this medical product! My medical choice is my right, at least up until now! I have just recovered from the Delta strain and now have natural immunity. I have been following the Democratic party-led efforts to do away with medical exemptions of any kind for the past six years. There is ample, good, medical research available to all of us, including yourselves, albeit outside the narrative being pushed by yourselves and Dr Ansorg.

I am also a lifelong Californian, but I barely recognize this state as of late, given the dictatorial nature that CA state politics, especially locally, has held sway in particular on this issue. I am equally appalled that you are choosing to create a two- tiered society, based on your political maneuvering to create laws that make it increasingly impossible for those citizens who do not choose your medical mandates to live equally with those who do under the law. This is not America, or American!

Based on the positions of each of you on this board, since the beginning of this Covid fiasco, (I have been following closely) I do not hold out much hope that you will change your position. I do, however, want this letter of communication to go down on record as a vote against all of you for this egregious act of treason leveled against local citizens. I for one, refuse to wear your blue star nor live as a second-class citizen in California!

Most Sincerely,

Oscar Carmona